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(Falls die Bezeichnung der Erfindung nicht angegeben ist, siehe Beschreibung.
If no title is shown please refer to the description.
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Dose delivery system

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Dose Delivery System

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03. März 2004

5 The present invention is directed to a unit dose delivery system for flowable substances. The delivery system or applicator of the present invention allows storage, mixing and well-controlled dispensing of multi-material component substances.

10 As dose delivery systems, standard syringe configurations are generally used. One of the drawbacks of standard syringe configurations is that syringe configurations having finger plates for material dispensing require a change of hand position when switching between dispensing and treatment. This can pose an inconvenience to the dentist. There are also syringe tips on the market for treating teeth which can be adapted to standard syringes (e. g. using Luer-lock
15 coupling). However, those tips are generally used only to spread substances on a surface and may not be adequate for providing sufficient mechanical force to the surface.

20 Further, some delivery systems do not have a means for storing and mixing material components and, therefore, may be inconvenient when delivering substances which are made of material components that have to be mixed just before use. In this case, the material components have to first be mixed and then filled into the system. This represents a disadvantage in terms of length of preparation and clean-up.

25 Further, some delivery systems, which enable storage and mixing of multi-material component substances, do not have adequate sealing means for the material components.

30 Therefore, there is a need for an improved dose delivery system and method offering improved handling, minimal effort for preparation and flexibility in terms of providing both controlled delivery and application of the substance.

The object of the present invention is to provide improved systems and respective methods. This object is achieved with the features of the claims.

- 5 The present invention is advantageous in that the delivery system is designed to allow dispensing and possibly treating using a single hand and without changing hand position. The present invention can be designed to be held like a pen or a dental instrument.
- 10 The present invention is advantageous in that the delivery system provides precisely-controlled dispensing of a substance.

The present invention is advantageous in that material components for substances can be pre-filled and stored in the delivery system and then mixed
15 automatically within the system prior to or during use. Therefore, there is no effort for preparation. Also, since the delivery system of the present invention is disposable, there is no effort for cleaning the system after use.

The present invention is flexible in that a delivery system is provided which can
20 also be used for cases where mixing and dispensing have to be separate procedures, i.e. two-step procedures.

The present invention also provides advantageous designs for tightly sealing the material components using foil only, thereby eliminating the need for using
25 additional parts, such as plug sealants.

Further advantages will be apparent from the following description and drawings of the preferred embodiments of the present invention:

- 30 **Figure 1** is a perspective view of an embodiment of the delivery system of the present invention.

- Figure 2** is another perspective view (from below) of the embodiment shown in Figure 1.
- Figure 3** is a cross-sectional view of an embodiment of the delivery system of the present invention.
- 5 **Figures 4A** is a cross-sectional view of an embodiment of a sealing means for the present invention in a closed position.
- Figures 4B** is a cross-sectional view of an embodiment of a sealing means for the present invention in an open position.
- 10 **Figure 5** is a perspective view of another embodiment of the delivery system of the present invention.
- Figure 6** is a perspective view of an embodiment of the present invention having an additional reservoir.
- Figure 7** is a schematic diagram of an embodiment of the present invention having an additional reservoir.
- 15 **Figure 8** is a prospective view of an embodiment of the present invention illustrating sealing means.
- Figure 9** is an illustration of material component flow in an embodiment of the self-opening closure system of the delivery system of the present invention.
- 20 **Figure 10** is an illustration of material component flow in another embodiment of the self-opening closure system of the delivery system of the present invention.
- Figure 11** is a cross-sectional view of an embodiment of the present invention with an embodiment of the self-opening closure system.
- 25 **Figure 12** is a perspective view of an embodiment of the present invention with sealing means.

Figure 13 is a perspective view of an embodiment of the present invention with sealing means.

In one preferred embodiment of the present invention as shown in Figures 1 and 2, the delivery system 10 generally comprises a cartridge 20 having two
5 compartments 22, 24 for storing material components and mixing means for mixing the material components, a plunger 30 having pistons 32, 34 associated with and corresponding to material compartments 22, 24, and actuating means for enabling controlled dispensing of the mixed material substance.

10 The cartridge 20 of the delivery system 10 has a body which is preferably made of relatively stiff material, for example polyoxymethylene. As shown in a cross-sectional view of the cartridge 20 in Figure 3, the cartridge 20 comprises a mixing means and material compartments 22, 24. The compartments or
15 chambers 22, 24 provide means for storing material components or substances in separate areas within the delivery system. This allows the system to pre-fill and store material components until use. Although only two material compartments are shown in the various described embodiments, it would be possible to have more than two material compartments containing different material components, if desired. Each material compartment 22, 24 is in fluid
20 communication at one end with the mixing means of the cartridge 20 such that when actuated the material components are transferred into the mixing means. The mixing means comprises a mixing barrel 26 and a mixer for mixing the material components. Preferably, the mixer comprises a static mixer 28 for passively mixing the components, wherein the material components are mixed
25 as these components flow within the mixing barrel 26 and through the static mixer 28.

Once activated, the plunger of the delivery system of the present invention primarily serves to apply pressure to the material components contained within
30 the compartments of the cartridge, thereby causing the material components to flow into the mixing means of the cartridge where the components are mixed. While deactivated, the plunger of the delivery system may serve as a sealing

means for the back ends of the compartments. The plunger 30 of the delivery system 10 is preferably made of relative soft elastic material, for example high density polyethylene. As shown particularly in the embodiments of Figures 3 and 5, the plunger has two sliding members in the form of pistons 32, 34 and possibly a surface 36 connecting the pistons 32, 34 at one end. Alternatively, the connecting surface 36 can be replaced with any means enabling the pistons to move uniformly. The pistons 32, 34 are designed to fit tightly and slideably into corresponding material compartments 22, 24. As seen in Figures 4A and 4B, each piston 32, 34 has a bulge 32a, 34a at its front end side forming a press fit with the material compartment 22, 24 thus providing a tight seal at the back end of the compartment. The other end or front end of the material compartment 22, 24 is in fluid communication with the mixing barrel 26 and sealed by a sealing means until the plunger 30 is actuated.

15 In order to prevent the material components from entering the mixing means before use, the delivery system of the present invention preferably comprises a sealing means. The sealing means should provide tight sealing of the compartments such that the material components are prevented from entering the mixing means before the plunger is actuated and should also allow flow of the material components into the mixing barrel once the plunger is actuated. One embodiment of the sealing means is shown in Figures 4A and 4B. In this embodiment, the sealing means comprises plugs 60 which are adapted to fit within outlets 22a, 24a at the front ends of the material compartments 22, 24. The plugs 60 serve to seal the outlet bores of the compartments, thereby preventing the material components from flowing into the mixing barrel 26 of the mixing means. The plugs 60 are preferably made of relative soft elastic material, for example high density polyethylene. The plugs 60 can be integrally molded together with the mixer 28 of the mixing means. Upon movement of the plunger 30 toward the front end the cartridge, the plugs 60 are pushed forward in the same direction as the plunger is moved thereby opening the outlets 22a, 24a and enabling the material components in the compartments 22, 24 to flow into the mixing barrel 26.

Also, conventional sealing means may also be used for the delivery system of the present invention. For example, the sealing means described in ?? RO/ DENT 159 and 171 as well as 185 ? would also be appropriate to tightly seal
5 the material compartments.

An embodiment of the actuation means of the present invention is illustrated in Figure 1. Here, the actuation means comprises a lever 52 integrally formed with the cartridge 20 and a geared connection rod 54 integrally formed with the
10 plunger 30. The lever 52 has a pawl 56 which engages with teeth or slots located on the connection rod 54. Upon each push of the lever 52, the pawl 56 is bent which causes the edge of the pawl 56 to move in the direction of the longitudinal axis of the system 10 thus forcing the connection rod 54 to move clockwise forward. As a result, the plunger 30 is moved forward thereby causing
15 the material components to flow into the mixing means and afterwards to exit as a mixed substance through the outlet of the cartridge 20. So each time the lever 52 is pushed, a small predetermined amount of material substance is extruded out of the delivery system thereby providing controlled delivery of the substance.

20

When the cartridge 20 is made of a relative stiff elastic material (e.g., polyoxymethylene), the lever 52 and pawl 56 will reset to their original positions after each push which makes additional retaining springs unnecessary.

25 Preferably, the delivery system of the present invention comprises a nozzle 40 provided at the outlet of the cartridge 20, as shown in Figures 1-3 and 5-6.

The delivery system of the present invention may be also used for treating the teeth, especially in cases where repeated or continuous delivery of substance to
30 the area to be treated is required or desirable during treatment. This eliminates the need to use separate instruments for application and treatment. To this end, the present invention may also comprise a means for treating teeth. The means

for treating teeth is preferably designed to apply considerable mechanical force to the surface to be treated.

5 The means for treating teeth preferably comprises a brush. It has so far been proven advantageous to have the fibers or bristles of the brush 45 be arranged in the outlet bore of the nozzle 40 of the system, as shown in Figure 6. Preferably, a bundle of straight fibers is formed by a press fit with the inner bore of the nozzle. The fibers are preferably made of PBT (polybutylene terephthalate) in order to achieve a relatively high stiffness for the brush. Other
10 optional materials for the fibers comprise PA (polyamide), POM (polyoxymethylene), COC (cyclo olefine copolymer) and LCP (liquid crystal polymers). The diameter of the bundle is preferably 1.5 mm, and most preferably within the range of 1 to 2 mm. The diameter of the individual fibers is preferably 0.25 mm, and most preferably within the range of 0.1 to 0.5 mm. The
15 length of the brush is preferably between 1 and 3 mm.

The brush 45 can be manufactured by any conventional means known in the art. For example, the brush 45 can be manufactured by integrally-molding the bristles and nozzle, by two shot injection molding the bristles and nozzle, or by
20 flocking bristles on a ball-shaped tip.

In one aspect of the present invention, a delivery system is provided which enables a two-step procedure. Such a delivery system may be preferred when mixing and dispensing of the materials have to be separate procedures. In some cases it may be advantageous to mix the material components in a first
25 step thereby activating the materials and forming a mixed substance and, then, to dispense the mixed substance in a second step. For example, when using a static mixer, the efficiency of the mixing depends on the flow rates of the material components flowing through the mixer. In order to achieve a more homogeneous mixing, a more or less rapid activation than achieved using a
30 static mixer may be desirable.

This aspect of the present invention is particularly described in Figures 5, 6 and 7. Each embodiment of this aspect of the present invention comprises an

additional reservoir 170, 270, 370 for receiving the mixed substance after it exits the mixing means of the cartridge 20. The mixed substance is then dispensed from this reservoir 170, 270, 370.

5 Further, in each of the embodiments of this aspect of the present invention, movement of the material components from the compartments into the mixing means is achieved by pushing the plunger 30 forward in the direction of the front end of the cartridge 20. This causes the material components to flow through the mixing means and to be activated as they mix.

10

Further, in each of the embodiments of this aspect of the present invention, the actuation means for mixing the material components is separate from the actuation means for dispensing the mixed substance and, therefore can be operated independently from each other. This enables the delivery system to be
15 used in a two-step procedure wherein the material components are first mixed and stored in a reservoir and then dispensed from the reservoir in a later step.

In one embodiment of this aspect of the present invention as shown in Figure 6, the delivery system 100 comprises a reservoir means for receiving and holding
20 the mixed substance. The reservoir means is attachable to the outlet of the cartridge 20 of the delivery system 100. The reservoir means comprises a bladder 170, preferably in the form of a soft blister. The bladder 170 may be manufactured by any conventional method, for example, by blow molding. The bladder 170 is squeezed out by a lever 152 that is step by step pushed from an
25 initial position to its end position. The lever is mechanically disabled from moving back into its initial position, thereby having a locking mechanism in one direction. Each time the bladder 170 is squeezed by the lever 152, a predetermined amount of mixed substance is extruded from the bladder 170 thereby providing controlled delivery of the mixed substance.

30

In a second embodiment of this aspect of the present invention as shown in Figure 5, the delivery system 200 also comprises a reservoir for receiving and holding the

mixed substance. Preferably, the reservoir is formed by the outer surface of the cartridge 20 and the inner surface of a movable sleeve 270, wherein a cavity is preferably formed therein. For dispensing the mixed substance, the cartridge 20 is moved into the sleeve 270 thus forcing the mixed substance out through the nozzle 40 of the system 200. Movement of the cartridge is done by actuation means. Here, the actuation means preferably comprises a lever 252 integrally formed with the movable sleeve 270. Slots are preferably formed on the cartridge 20. Preferably, the lever 252 has a pawl 256 which engages with the slots of the cartridge 20. Upon each push of the lever 252, the pawl 256 is preferably bent which causes the edge of the pawl 256 to move in the direction of the longitudinal axis of the system 200 thus forcing the cartridge 20 to move forward. Preferably, the lever 252 and pawl 256 are integrally made with the sleeve 270 using a one shot molding technique.

A third embodiment of this aspect of the present invention is shown in the schematic diagram of Figure 7. In this embodiment, the delivery system 300 also comprises a reservoir for receiving the mixed substance after it exits the mixing means of the cartridge. As shown in Figure 7, the delivery system 300 preferably comprises a dispensing means coupled to the outlet of a cartridge. The cartridge has preferably two compartments for storing material components and a mixing means for mixing the components. Preferably, the cartridge is activated by pressing the plunger forward into the mixing means. After exiting the mixing means, the mixed substance of material components may enter the dispensing means. Preferably, the dispensing means comprises actuation means and a reservoir 370 for receiving and holding the mixed substance. The actuation means preferably comprises a lever 352, a pawl 356, a connecting rod 356 and a plunger 332 having a piston. By pressing the lever 352, the plunger 332 is activated and the piston of the plunger 332 is caused to move forward into the reservoir 370 thereby pushing the mixed substance forward into the nozzle 340 where the substance can be dispensed. Preferably, the dispensing means is adapted to provide precise dispensing of the substance. One of the advantages of this embodiment is that the delivery system does not shorten in length while dispensing.

In another aspect of the present invention, the delivery system 10, 100, 200, 300 comprises sealing means and a self-opening closure system as illustrated in Figures 8 – 13. The self-opening closure system can be used, for example, as an alternative to the sealing means described in Figures 4A and 4B.

Figure 8 shows a sealing means of the present invention using a sealing material to seal the material compartments of the cartridge. The sealing material is preferably foil. In this case, the pistons are preferably used only to push the material components. In one embodiment of the sealing means, the pistons are sealed in the compartments together with the material components. The plunger further comprises two pin rods that are preferably shaped like sharp pins. The pin rods are used to penetrate the foil easily and then to push the pistons forward. In another embodiment, pistons are not used. Rather, the pin rods of the plunger are used to penetrate and push the foil forward thereby also pushing the material components forward. It has been found that, although the foil is penetrated by the pin rods, both of these embodiments properly sealed the material components as they are moved forward. In other words, there was no lost of material components, for example, due to the material seeping out around the pistons or pin rods.

The present invention also comprises a self-opening closure system at the front ends of the compartments. The closure system is self-opening in the sense that the closure system seals the front ends of the compartments until the plunger is activated thereby restricting the material components from flowing into the mixing means and opens when sufficient pressure is exerted by the material components which are pushed forward by the plunger when activated. The closure system preferably comprises at least one sealing material, at least two outlet bores connected to the material compartments and at least one inlet. The sealing material is permanently sealed along the circumference of an area at the front end of the cartridge. The permanently sealed area surrounds a non-permanently sealed area. As shown in Figure 9, the sealing material can be

For example, one preferred embodiment of the invention is described in Figures 11-13. In this embodiment, the delivery system comprises an embodiment of the self-opening closure system combined with the embodiment described in Figure 6 having an additional reservoir in the form of a bladder. However, the
5 sealing features of this embodiment can also be used in combination with any of the embodiments of Figures 1-3, 5 and 7.

In this embodiment of the present invention, the cartridge has preferably grooved-shaped material compartments. As shown in Figure 11, the grooved-
10 shaped compartments preferably taper from the front to the back end of the cartridge in order to provide optimal emptying of the compartments. Also, as seen in Figure 11, the cartridge preferably further incorporates the base of a self-opening closure system as described above.

15 The grooved-shaped compartments filled with the material components are preferably covered and sealed by a sealing material, as shown in Figures 12 and 13. A sealing material preferably extends from the back end to the front end of the cartridge and preferably covers both material compartments and the closure system. As seen in Figures 12 and 13, the plunger has preferably two
20 pistons or bulges for sliding into the grooves and pressing the sealing material covering the compartments. Preferably, the pistons are cylinder in shape and correspond to the shape of the grooved compartments. As the plunger is pushed forward, the bulges press the sealing material into the grooves thereby displacing and moving the material forward toward the self-opening closure
25 system. Preferably, an actuation means as used in the embodiment of claim 6 is used also for precise dispensing of the mixed substance in this embodiment.

The present invention is not limited to the specific illustrated embodiments. Moreover, the present invention is realized by the features of the claims and
30 any obvious modifications thereof.

E.
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08. März 2004

CLAIMS

- 5 1. A delivery system for controlled dispensing of a substance, the system comprising:
- a cartridge having at least two compartments for storing material components and a mixing means for mixing the material components to form a substance;
- 10 a plunger for causing the material components to flow into the mixing means, the plunger having at least two pistons for sliding correspondingly into the at least two compartments;
- and
- actuation means for providing controlled dispensing of the mixed
- 15 material components.
2. The delivery system according to claim 1, further comprising
- reservoir means for receiving the substance exiting the mixing
- 20 means of the cartridge, wherein the reservoir means is compressible by the actuation means.
3. The delivery system according to claim 2, wherein
- the reservoir means comprises a bladder attachable to an outlet of
- 25 the cartridge and
- the actuation means comprises a lever for pressing the bladder in a continuous and/or stepwise manner such that, with each press of the bladder by the lever, a predetermined amount of substance can be

extruded from the bladder thereby providing controlled dispensing of the substance.

4. The delivery system according to claim 2, wherein

5 the reservoir means comprises a sleeve which is movable over the exterior surface of the cartridge and a cavity for receiving the substance exiting the cartridge, the cavity being formed by the interior surface of the sleeve and the exterior surface of the cartridge.

- 10 5. The delivery system according to claim 4, wherein

the actuation means comprises a lever having a pawl, the lever being attached to the sleeve, the pawl engaging with the cartridge and the actuation means being operable in a stepwise manner such that when the pawl engages the cartridge, the cartridge is caused to move
15 forward toward the cavity thereby extruding the substance from the cavity and providing controlled dispensing of the substance.

6. The delivery system according to claim 2, wherein

the reservoir means comprises a chamber for receiving the
20 substance, the chamber being attachable to the outlet of the cartridge, and

wherein the actuation means comprises a lever, a connecting rod and a piston attached to the connecting rod and slideable into the chamber, the actuation means being operable in a continuous and/or
25 stepwise manner such that when the lever is engaged, the connecting rod is caused to move and to drive the piston forward into the chamber thereby causing a pre-determined amount of the substance to be extruded from the chamber.

- 30 7. A sealing system for sealing a cartridge of a delivery system, the system comprising:

a sealing material;

a cartridge having at least two compartments for storing material components, the at least two compartments being sealed by the sealing material; and

5 a plunger having at least two pin rods for corresponding to the at least two compartments;

wherein, as the plunger is moved forward, the at least two pin rods are adapted to penetrate the sealing material thereby pushing the material components within the compartments forward toward the front of the cartridge such that tight sealing is provided where the sealing material is
10 penetrated by the pin rods.

8. The sealing system according to claim 7,

wherein the plunger further comprises at least two pistons, the at least two pistons being located within the respective compartments
15 behind the sealing material;

wherein, as the plunger is moved forward, the at least two pin rods are adapted to penetrate the sealing material and to contact the corresponding pistons and to thereafter push the pistons forward thereby pushing the material components forward toward the front of the
20 cartridge

9. A method of sealing a cartridge for a delivery system, the method comprising:

25 providing a sealing material;
providing a cartridge having at least two compartments for storing material components;

placing the sealing material over the length of the at least two compartments thereby sealing material components with the compartments;

30 providing a plunger having at least two pin rods corresponding to the at least two compartments;

moving the material components within the compartments by pushing the plunger forward,

5 wherein, as the plunger is pushed forward, the at least two pin rods penetrate the sealing material thereby pushing the material components within the compartments forward toward the front of the cartridge such that tight sealing is provided where the sealing material is penetrated by the pin rods

10 10. A method of sealing a cartridge for a delivery system, the method comprising:

providing a sealing material;

providing a cartridge having at least two compartments for storing material components;

15 providing a plunger having at least two pistons for sliding correspondingly into the at least two compartments and at least two pin rods corresponding to the at least two pistons;

positioning a piston in each of the compartments of the cartridge;

20 placing the sealing material over the at least two compartments and the at least two pistons positioned within corresponding compartments thereby sealing the material components and pistons within the compartments;

moving the material components within the compartments by pushing the plunger forward,

25 wherein, as the plunger is moved forward, the at least two pin rods are adapted to penetrate the sealing material and to contact corresponding pistons underneath the sealing material and to thereafter push the pistons forward thereby pushing the material components within the compartments forward toward the front of the cartridge.

30 11. A self-opening closure system for a cartridge for a delivery system, the system comprising:

a cartridge having at least two compartments for storing material components and a mixing means for mixing the material components to form a substance;

a plunger having at least two pistons for sliding correspondingly into the at least two compartments; and

a sealing material for sealing the material components within the compartments;

wherein

the cartridge further comprises at least two compartment outlets corresponding to the at least two compartments and at least one inlet in fluid communication with the mixing means,

the at least two compartment outlets and inlet being sealed in an area underneath the sealing material, wherein the sealing material is permanently sealed along the perimeter of the area and non-permanently sealed in the area above the at least two compartment outlets and the at least one inlet such that, before the plunger is activated, the non-permanent sealing is sufficient to prevent the material components from exiting through the compartment outlets and/or from entering the inlet of the mixing means and such that, when the plunger is activated, the pressure caused by the material components pressing against the sealing material is sufficient to cause the non-permanent sealing to open thereby allowing the material components to exit through the compartment outlets and enter into the inlet of the mixing means.

12. The self-opening closure system according to claim 11,

wherein the cartridge comprises an inlet in fluid combination with an intermediate chamber, and

wherein, when the plunger is activated, the pressure caused by the material components pressing against the sealing material is sufficient to cause the non-permanent sealing to open thereby allowing the material components to exit through the compartment outlets and

enter the intermediate chamber before entering the inlet of the mixing means.

13. A method of sealing for a cartridge for a delivery system, the method comprising:
- 5 providing a cartridge having at least two compartments for storing material components and a mixing means for mixing the material components to form a substance;
- 10 providing a plunger having at least two pistons for sliding correspondingly into the at least two compartments; and
- providing a sealing material for sealing the material components within the compartments;
- 15 providing the cartridge with at least two compartment outlets corresponding to the at least two compartments and at least one inlet in fluid communication with the mixing means, the at least two compartment outlets and inlet being sealed in an area underneath the sealing material,
- 20 wherein the sealing material is permanently sealed along the perimeter of the area and non-permanently sealed in the area above the at least two compartment outlets and the at least one inlet such that, before the plunger is activated, the non-permanent sealing is sufficient to prevent the material components from exiting through the compartment outlets and/or from entering the inlet of the mixing means and such that,
- 25 when the plunger is activated, the pressure caused by the material components pressing against the sealing material is sufficient to cause the non-permanent sealing to open thereby allowing the material components to exit through the compartment outlets and enter into the inlet of the mixing means.
14. A delivery system for controlled dispensing of a substance, the system comprising:
- 30

a cartridge having at least two compartments for storing material components and a mixing means for mixing the material components to form a substance;

5 a plunger having at least two pistons corresponding to the at least two compartments; and

a sealing material for sealing the material components within the compartments,

10 wherein the at least two compartments are grooved-shaped and the at least two pistons are correspondingly shaped to the compartments, and wherein, as the plunger is moved forward, the pistons press an exterior surface of the sealing material as the pistons move forward which compresses the compartments so as to press the material components forward toward the front of the cartridge.

15 15. The delivery system of claim 14, wherein the circumference of compartments is tapered and the respective movement of the pistons correspond to the tapering.

20 16. A system and/or method according to any one of the preceding claims with further features being in combination or alone derivable from the figures.

25 17. The system according to any of the preceding claims, further comprising means for treating teeth.

18. The system according to claim 17, wherein the means for treating teeth comprises a brush.

30

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Case : VP-SYR PEN/EP
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Erfindung
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03. März 2004

ABSTRACT

Dose Delivery System

5 The present invention is directed to a unit dose delivery system for flowable substances. The delivery system or applicator of the present invention allows storage, mixing and well controlled dispensing of multi-material component substances.

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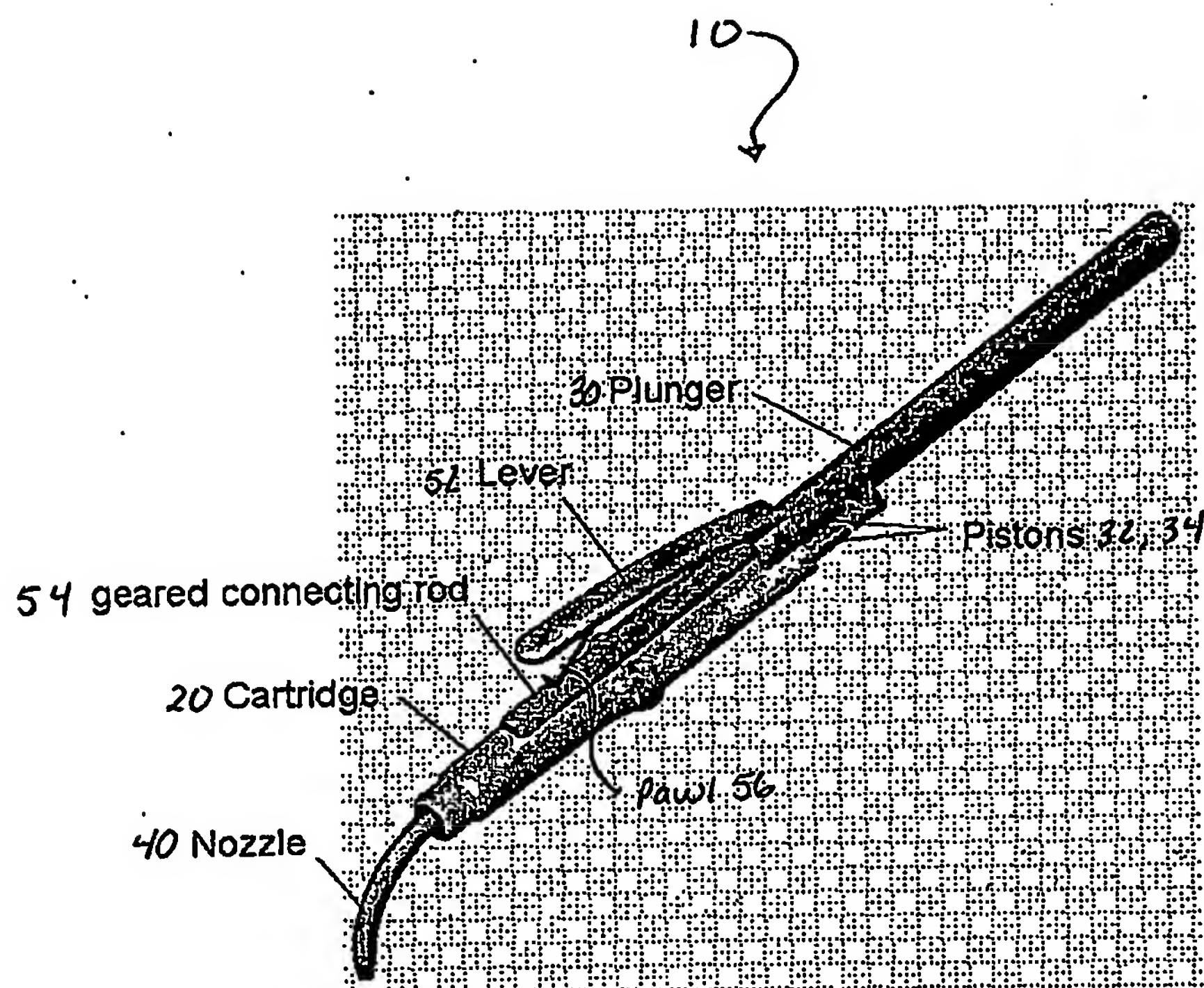


Figure 1

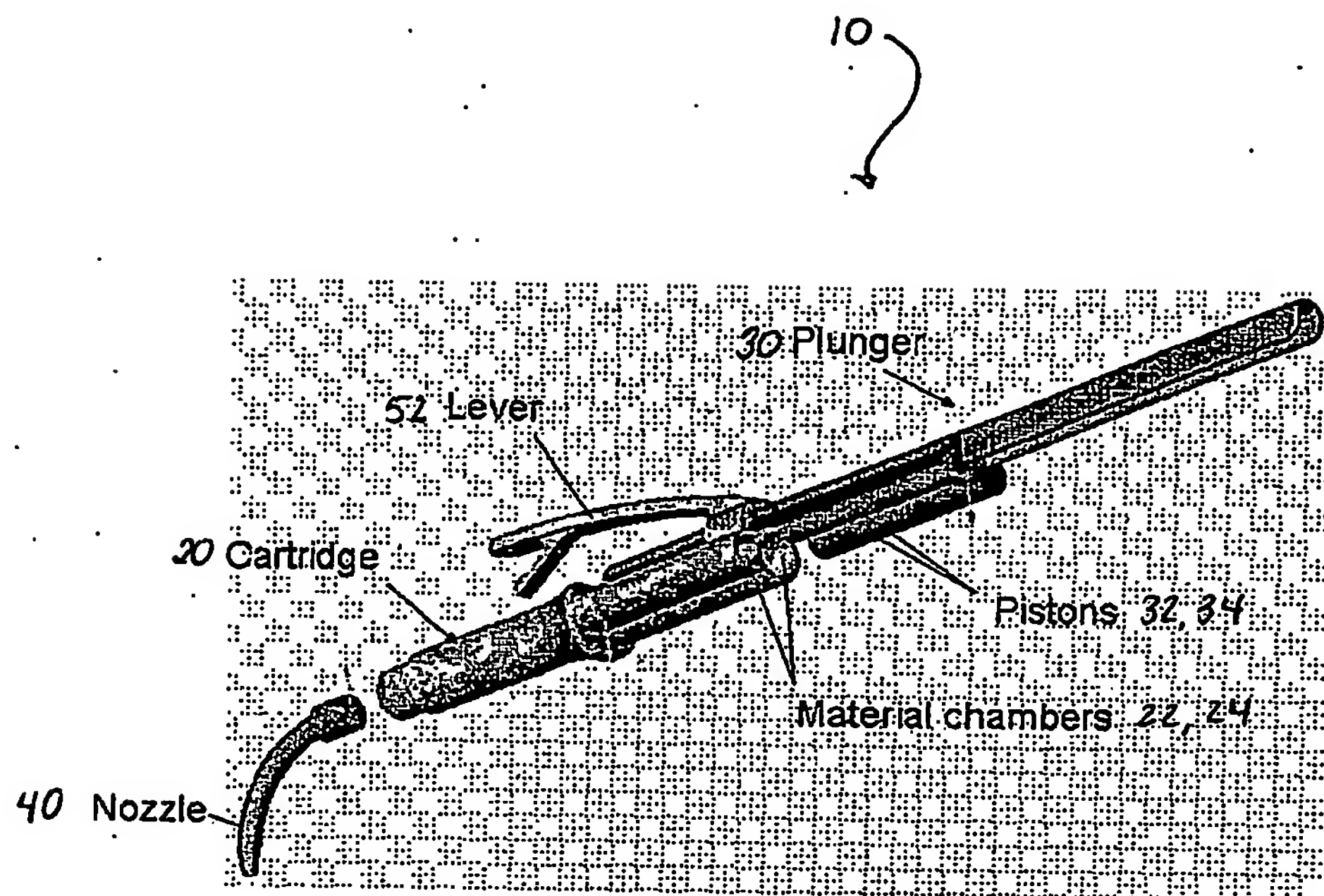


Figure 2

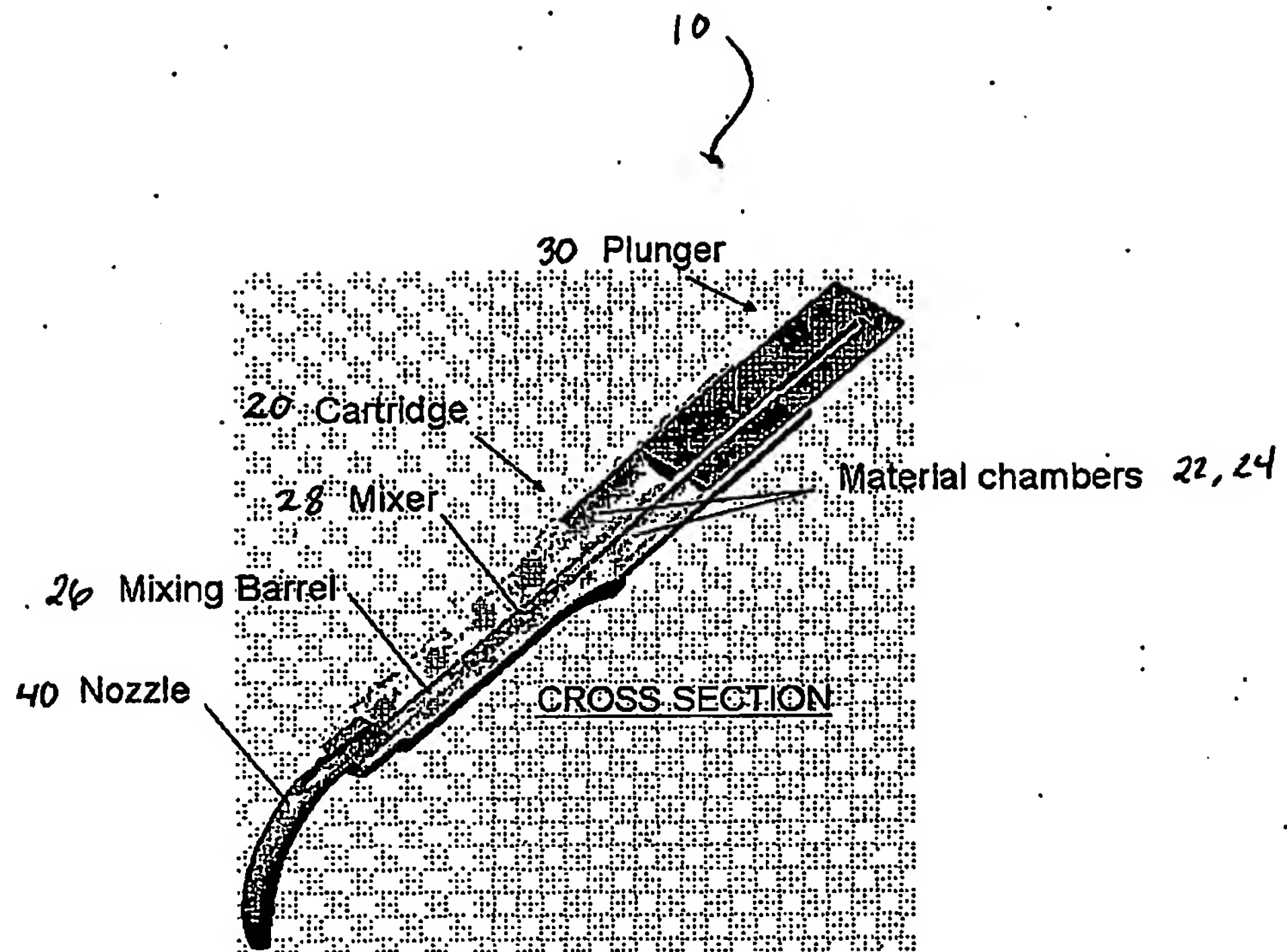


Figure 3

Fig. 4A

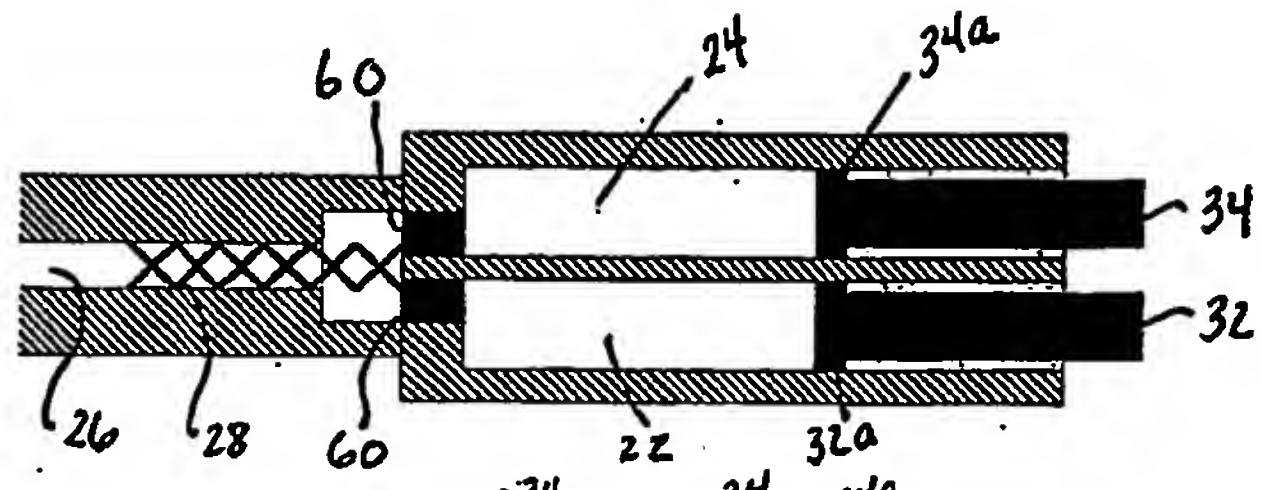
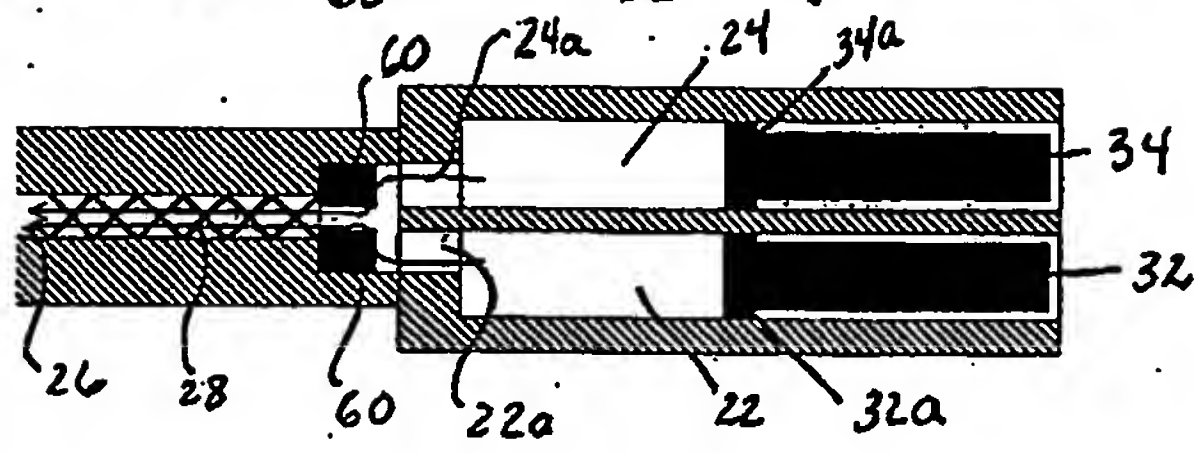


Fig. 4B



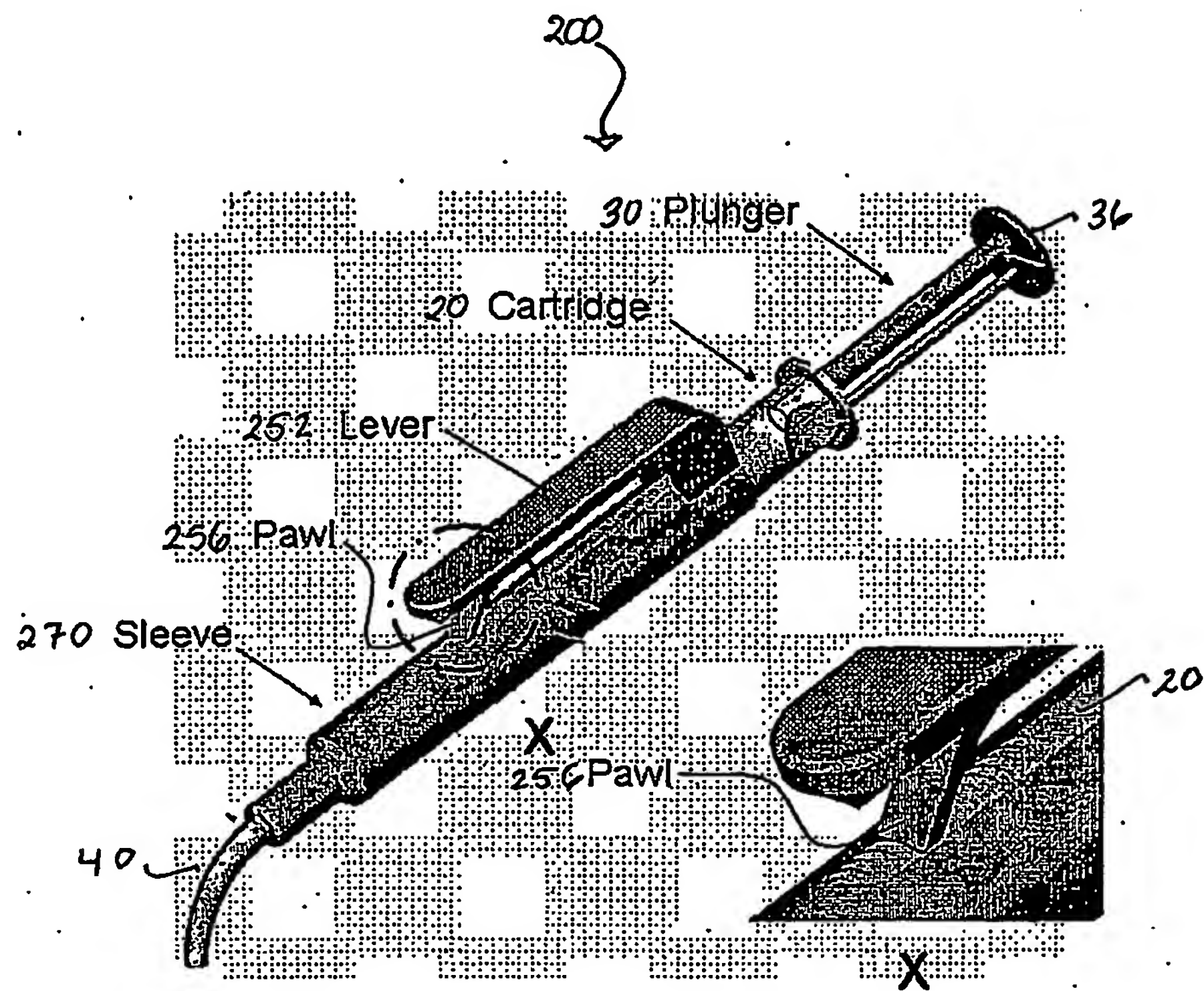


Figure 5

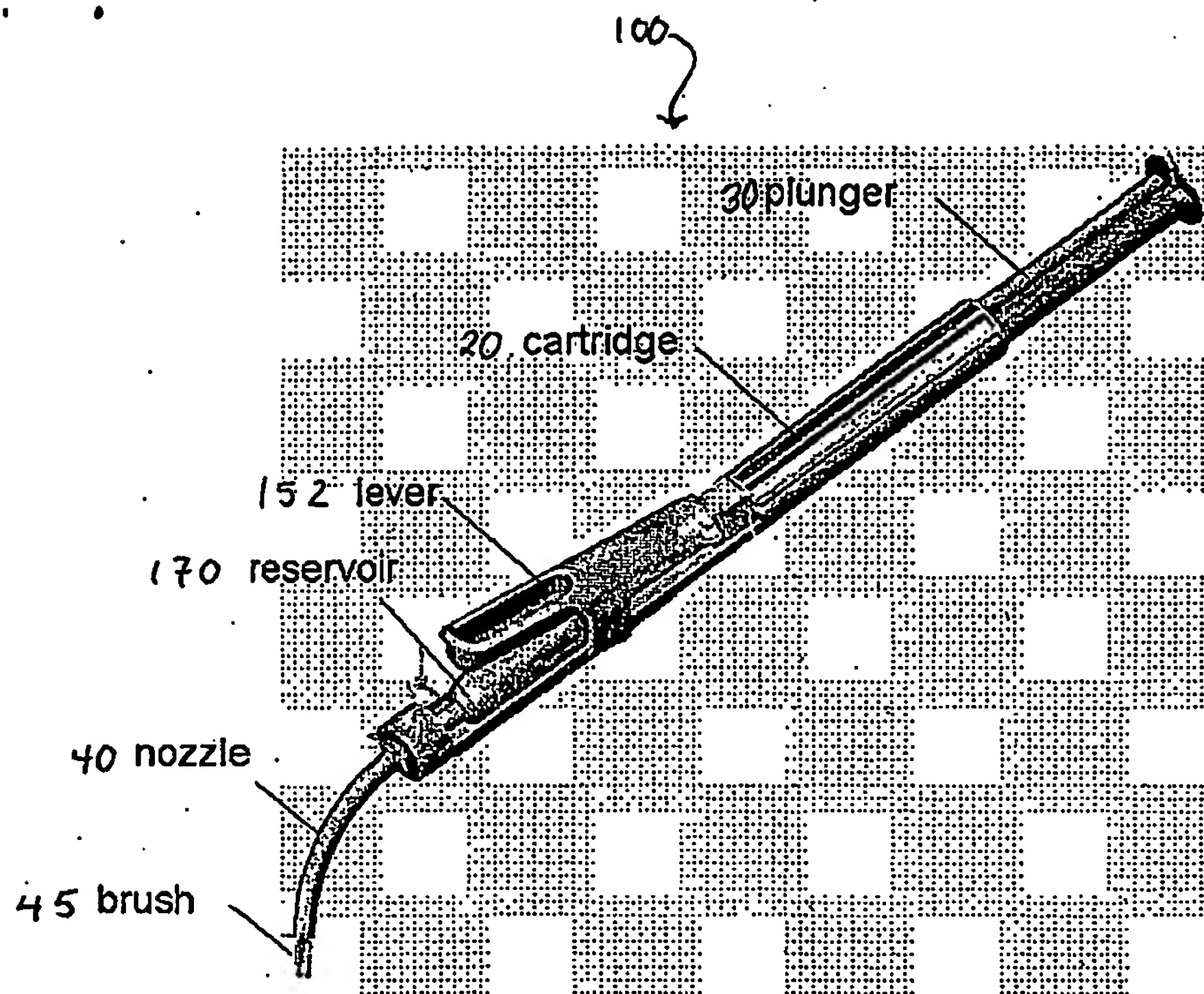


Figure 6

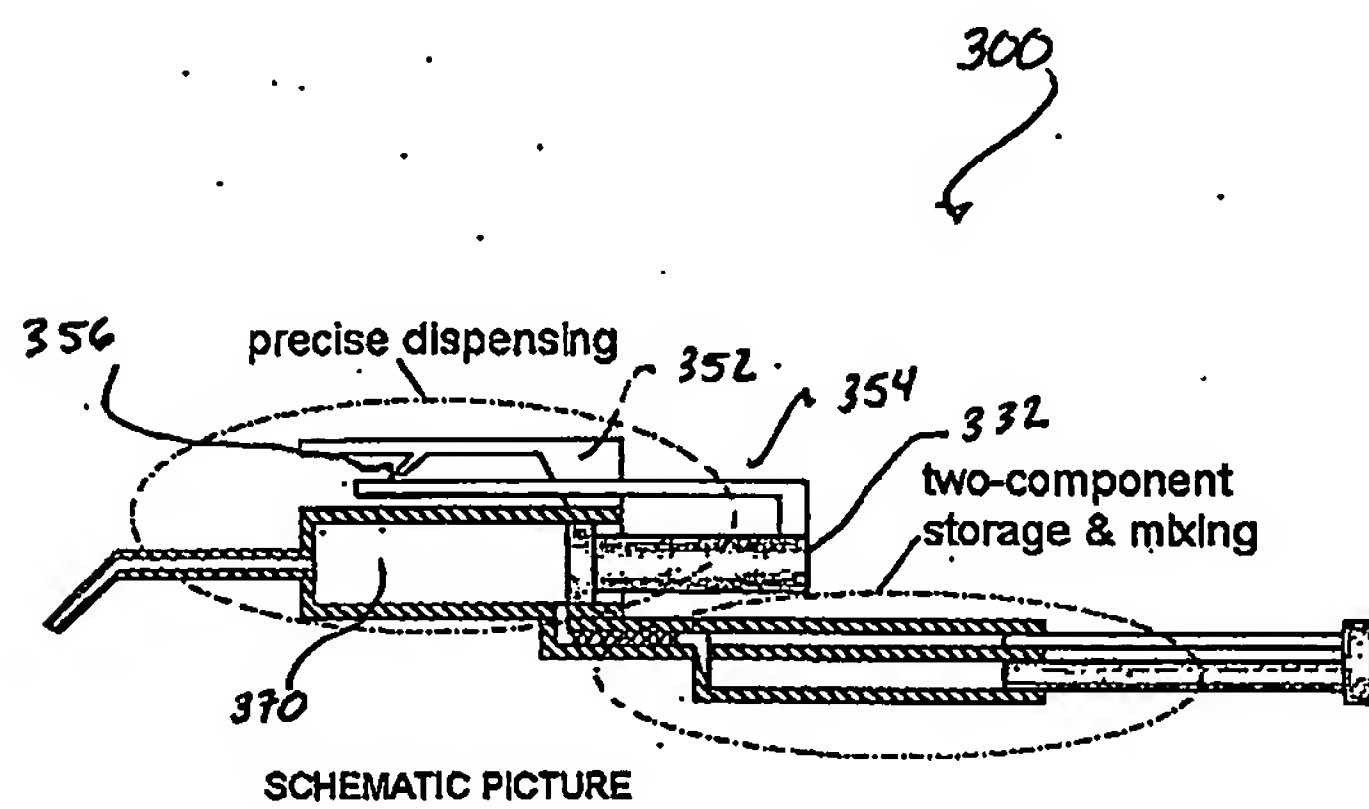


Figure 7

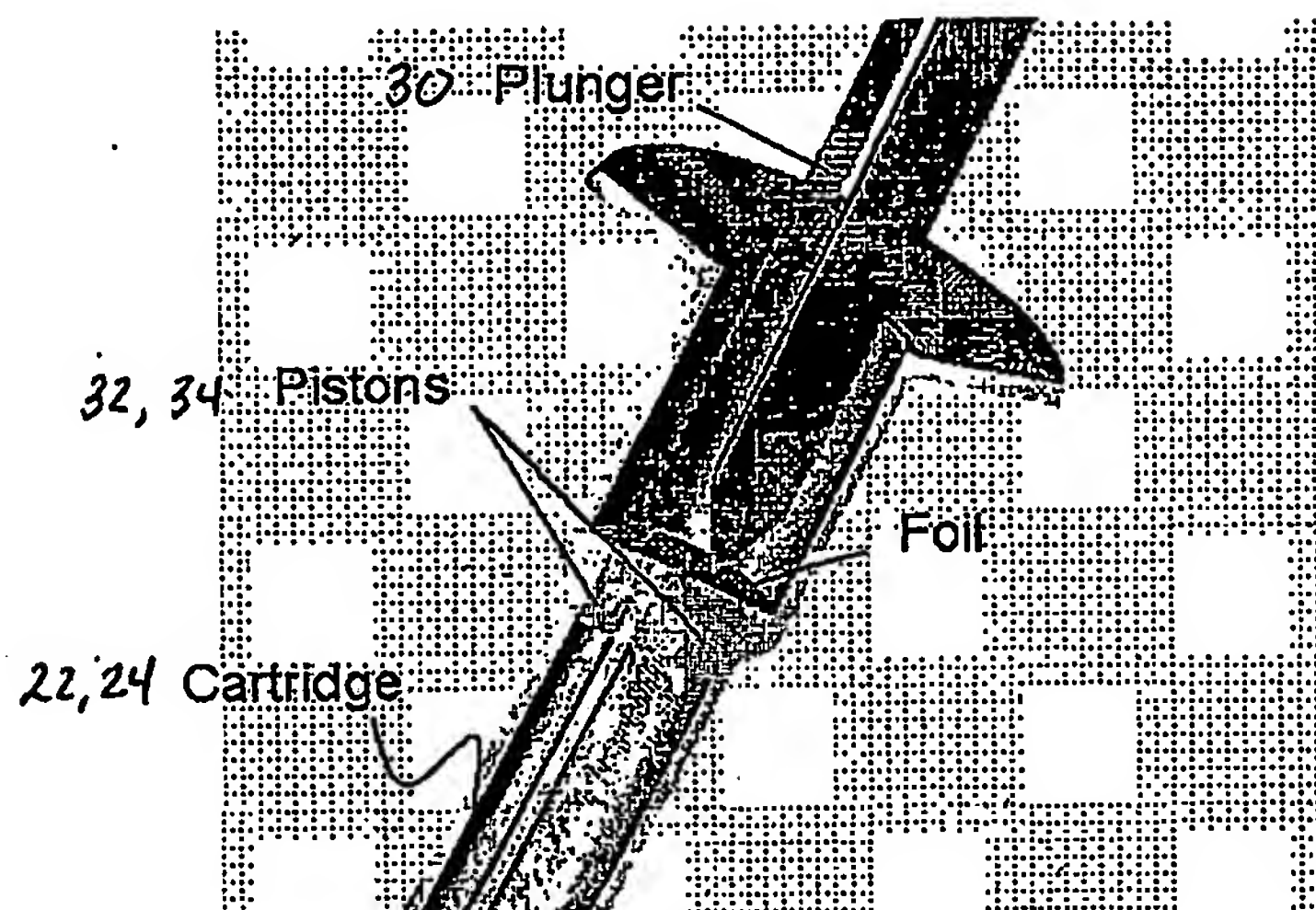


Figure 8

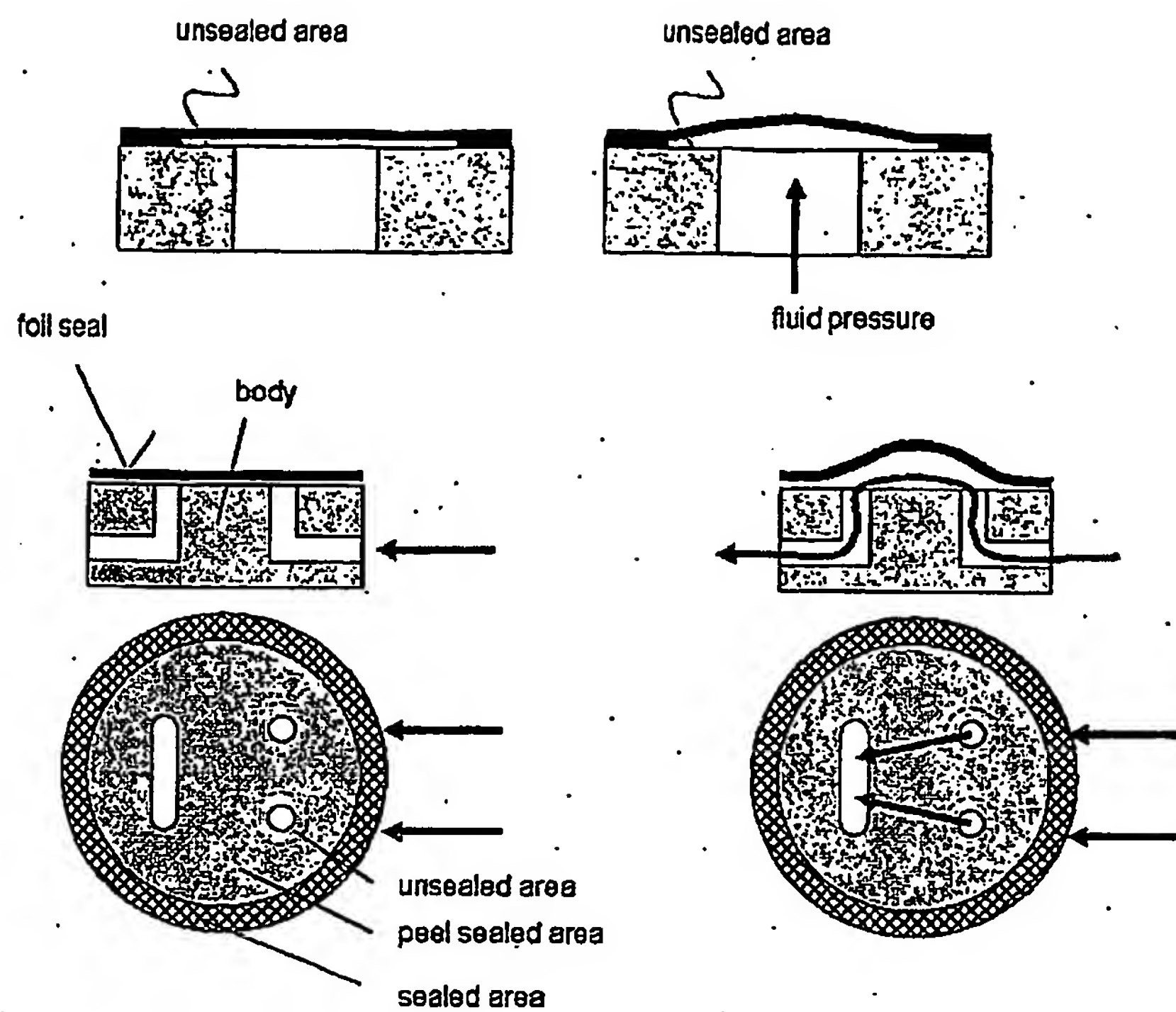


Figure 9

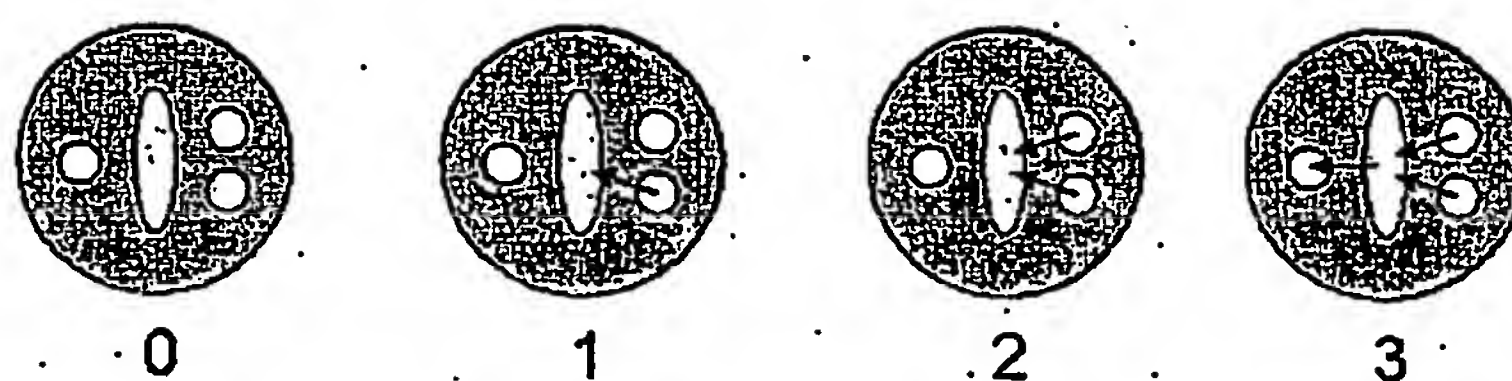


Figure 10

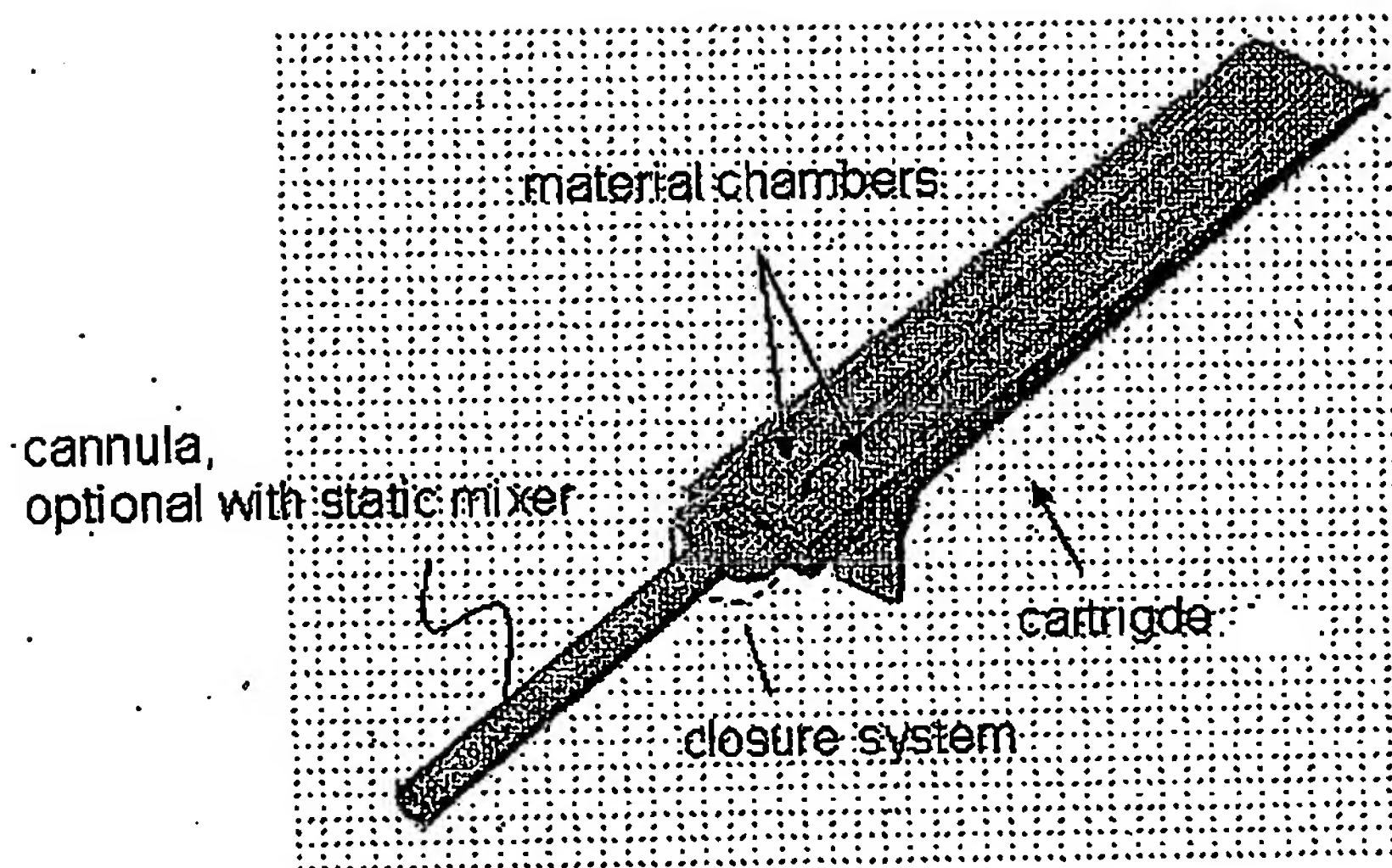


Figure 11

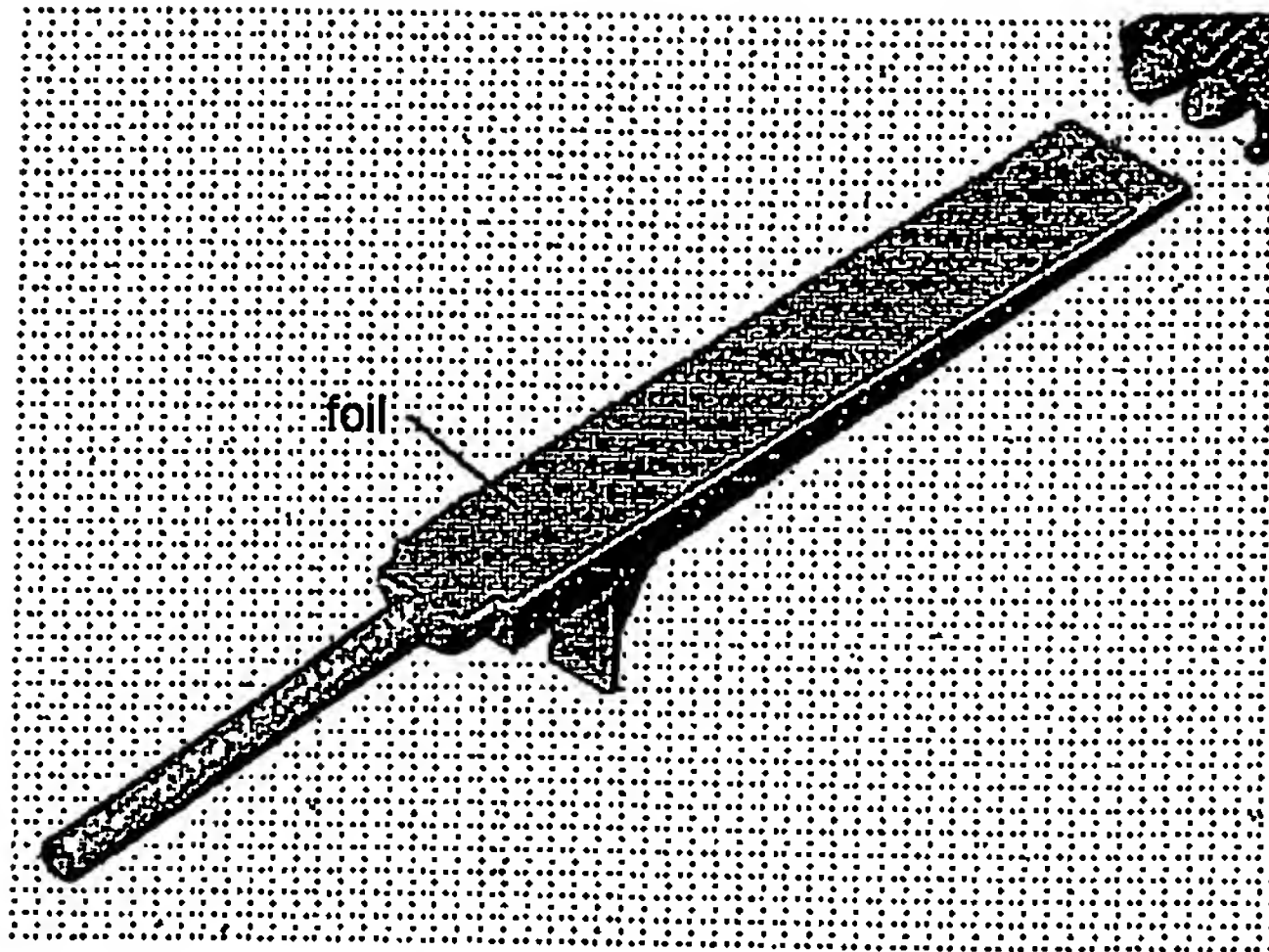


Figure 12

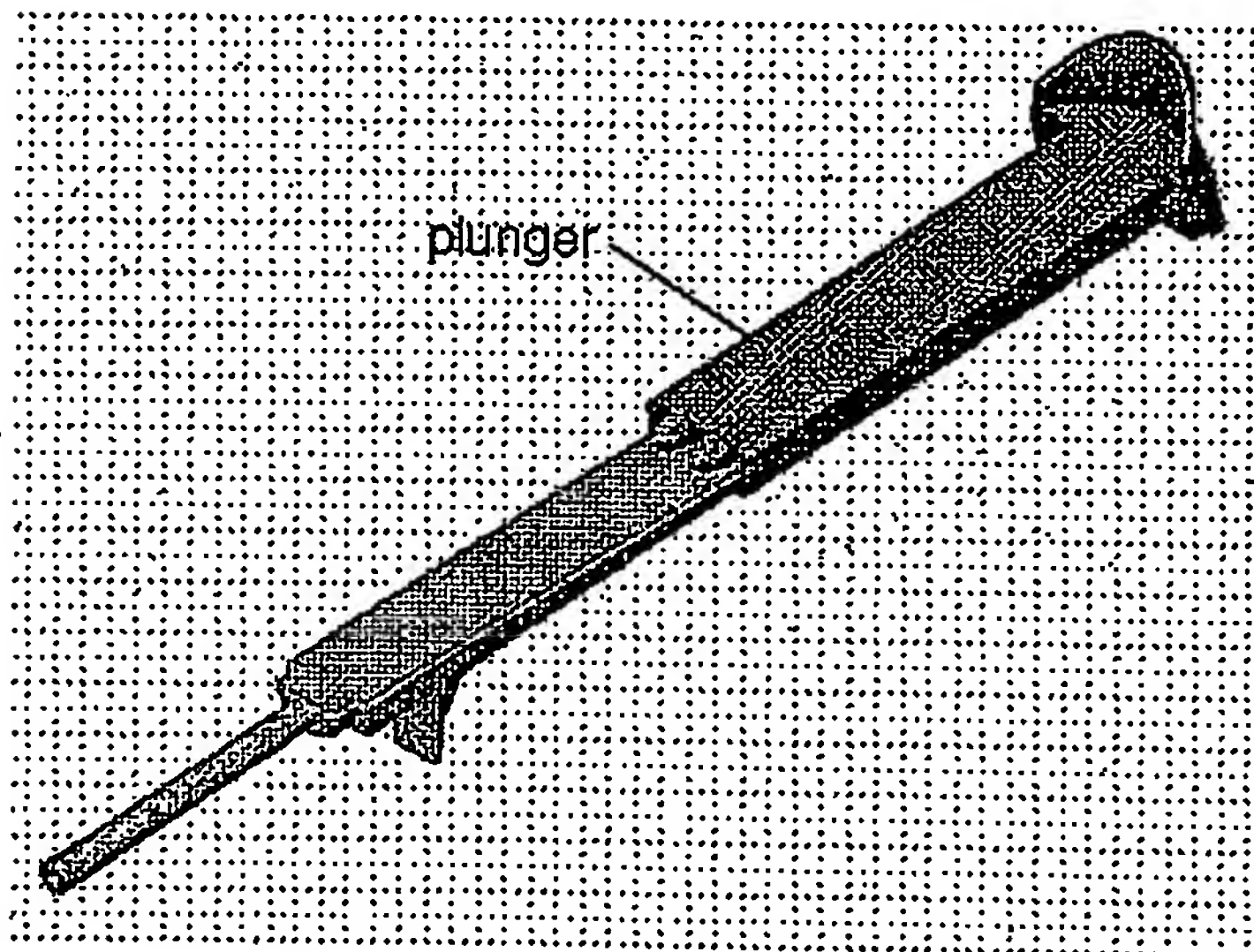


Figure 13